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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

10/14/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 09/848,225	<b>Applicant(s)</b> SHIROYAMA ET AL.	
	<b>Examiner</b> Lakshmi S. Channavajjala	<b>Art Unit</b> 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 29 July 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 7 and 12-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 and 12-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt of response dated 7-29-10 is acknowledged.

Claims 1-6 and 8- 11 have been canceled. Claims 7 and 12-29 are pending.

The following rejection of record has been maintained:

#### ***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 7 and 12-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,355,232 to Kaneko et al and EP 092852 (EP 252 submitted on PTO-1449 dated 1-27-03) in view of US 5,294,444 to Nakamura et al or Nakamura in view of Kaneko and EP 092852, and further in view of either one of JP-A-04-193814 ('814) or JP 63-192703 ('703).
3. The newly cited JP '814 and JP '703 references have been submitted by applicants on IDS dated 5-13-09.
4. Nakamura teaches a transparent or semi-transparent cosmetic composition comprising an amphipathic lipid, nonionic surfactant, ionic surfactant and an aqueous medium (abstract, col. 2, lines 1-18). Nakamura teaches the non-ionic surfactant of instant claim 13 (col. 3, lines 1-5 & tables 2 and 3), cholesterol and fatty acids (table 2). The amounts of ceramides, non-ionic surfactants, fatty acids and cholesterol in the composition taught by Nakamura are within the instant claimed ratios table 2). With respect to the claimed method step of mixing lipid composition while heating at 80 -120 degrees C and heating water at 80 to 100 degrees C, Nakamura teaches that the

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components of table 3 were mixed and melted at a temperature of 85- 90 degrees C (within the heating temperature of instant claims), followed by addition of hot water (Col. 4, lines 51-55). While Nakamura fails to state the specific temperature of water, absent evidence to the contrary, the term "hot water" includes boiling water, which is 100 degrees C or water as hot as 80 C. Nakamura also teaches that the compositions do not irritate the skin, as claimed (col. 1, lines 65-68).

5. Nakamura teaches ceramides, glycerocermides and ceramide derivatives, but does not teach the ceramides having the structural formula of instant claims. Nakamura fails to teach the claimed optically active compounds.

6. Kaneko teach skin and hair protective compositions comprising erythro (2S, 3R) type of ceramides having the structural formula I -VI (col. 2, lines 15 through col. 3, lines 57). In particular, the ceramides of structural formula I meets the claimed structure II of claim 15. Kaneko also suggests a combination of amphipathic surfactants such as fatty acids, fatty alcohols etc., and cholesterol or a phytosterol, in the composition (col. 3, lines 58 through col. 4, lines 28).

7. EP '852 teaches hair care compositions comprising at least one (2S,2R)-2-acylaminoalkane-1,3-diol compounds of formula I, where the variables R1 and R2 read on the variables described in the instant formula I of claim 7. In particular, the compounds that are claimed in the instant claims 18 and 21-26 are described in the compounds on page 7 of EP 852. EP also recognizes the ceramides compounds for retaining moisture and as a skin barrier ([0010]) in addition to using them for increasing the hair strength.

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8. Thus, all three references (Nakamura, EP and Kaneko) recognize the ceramides for their improved barrier functions in skin and hair applications.

9. It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to replace the ceramides of Nakamura, with the optically active ceramides of Kaneko and that of EP 252 because Kaneko as well as EP 252 teach that the optically active ceramides exert remarkable water-barrier functions in skin protection compositions, as opposed to the racemates and significantly higher water holding capacity than racemates and pseudoceramides (col. 1, lines 59-67 and col. 8, lines 10-15) and improve hair strength. Alternatively, a skilled artisan would have been able to employ the method of preparing transparent lipid compositions such as pseudoceramides of Nakamura in preparing the composition of Kaneko because Nakamura suggests that the compositions are stable and non-irritating.

10. Thus, a skilled artisan would have expected that the ceramides of Kaneko to function better than the ceramides or pseudoceramides of Nakamura. While Kaneko fails to teach the specific ceramides of claims 18-20, in the absence of establishing an unexpected result with respect to the specific active ceramides taught by Kaneko, one of an ordinary skill in the art at the time of the instant invention was made would understand from the teachings of Kaneko and EP that the 2S, 3R type of ceramides (optically active) are significantly more efficient in their skin moisturizing effect than the racemates and pseudoceramides because Kaneko teaches that the water restraining capacity of optically active ceramides is higher than the other ceramides (col. 8, lines 18-56).

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11. With respect to the new limitation “cosmetic additive”, all of the references cited teach cosmetic compositions and thus meet the limitation. It is unclear how instant composition can be an additive when the ceramides of the instant application are also taught for the same function i.e., protection of stratum corneum.

12. With respect to the limitation “free of ionic surface active agent”, applicants agree that Kaneko does not require surface active agent, which meets the claimed proviso limitation.

13. On the other hand, each of the newly added JP ‘814 and JP ‘703 references, teach ceramide compositions.

14. JP ‘814 shows a transparent cosmetic containing an amphipathic lipid, a nonionic surfactant and an aqueous medium (Claims) for the purpose of compounding an amphipathic lipid in a transparent state in a stable manner and of preparing a cosmetic having no risk of skin irritation (upper left column, page 2), exemplified ceramide as the amphipathic medium (upper right column, page 2), polyoxyethylene castor oil as the nonionic surfactant (upper left column, page 3) and water or a combination of water with water-soluble alcohols such as glycerin or 1,3- butanediol as the aqueous medium (lower left and lower right columns, page 3).

15. JP 703 discloses an oil-in-water type emulsified cosmetic in Example 4 in which 5.0% by weight of ceramide (bovine brain ceramide), stearic acid, polyoxyethylene (60) hydrogenated castor oil, glyceryl ether and water are compounded. Although said document does not teach that the composition in the Example is transparent, there is a high possibility that it is a transparent composition since the composition of the

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document is identical with that of the present application. Particularly in Examples 22 to 28, there is disclosed a lotion which contains an amide derivative, stearic acid/palmitic acid, polyoxyethylene hydrogenated castor oil, glycerin, cholesterol and water.

16. Thus, it would have been obvious for a skilled artisan at the time of the instant invention was made to anionic surfactants of Nakamura in the preparation of transparent stable composition because the references of JP 703 and JP 814 teach the preparation of ceramide composition without the need of anionic surfactants.

Furthermore, applicants have not shown any unexpected advantages of excluding ionic surfactant from the composition. On the other hand, the instant specification clearly states that one can employ anionic surfactants (including those described by Nakamura or EP 852).

### ***Response to Arguments***

17. Applicant's arguments filed 7-29-10 have been fully considered but they are not persuasive.

18. Applicants argue that none of the references cited either taken alone or in combination, disclose or render obvious the features of the instantly claimed method of preparing a clear aqueous cosmetic additive composition, as recited in claim 7 of the present application. It is argued that Nakamura teaches 1-50% by weight, based on (b), of an ionic surfactant, for preparing a transparent or semi-transparent cosmetic composition in which the amphiphatic lipids are stably microdispersed. (See Nakamura, Abstract). Applicants argue that Nakamura specifically discloses that component (C) is used in an amount of 1-50% by weight, preferably 2-30% by weight based on the weight

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of component (B) and that if the amount of the (C) is out of this range, the cosmetic composition will not be adequately transparent or semi-transparent. (See Nakamura, Col. 3, lines 55 to Col. 4, line 3). Therefore applicants argue that if one of ordinary skill in the art were to combine Nakamura with JP '814 or JP '703 to exclude the "ionic surface active agent" from cosmetic composition of Nakamura, as suggested by the Examiner, the obtained composition would not be transparent or semi-transparent. Hence, applicants argue that contrary to the Examiner's assertion, one of ordinary skill in the art would not be motivated to modify the cosmetic composition of Nakamura to exclude the ionic surface active agent, because the intended function of the cosmetic composition of Nakamura would be changed or impaired if modified to exclude the ionic surface active agent as suggested by the Examiner. Applicants argue that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). It is argued that the prior art must be considered in its entirety, including disclosures that teach away from the claims and the Examiner's assertion that the present rejection provides a motivation to exclude an ionic surfactant because of its skin and eye irritating properties is simply incorrect.

19. Applicants' arguments are not found persuasive because while Nakamura states that **a relatively small quantity of** a combination of nonionic and ionic surfactants result in beautifully transparent or semi-transparent and stable compositions, Nakamura also states that the use of large amount of surfactants tends to interfere with the



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functioning of the amphipathic lipids in a stable and clear transparent or semi-transparent conditions (col. 1). Nakamura emphasizes that if the ratio of A/B+C is less than 0.2, the amount of surfactant is so large that it results in skin irritation to the skin (col. 4, L 3-8). Nakamura teaches ionic surfactants in amounts as low as 1.0% (col. 2, L 13) and exemplifies compositions with 0.3%-0.5% ionic surfactants sodium polyoxyethylene lauryl ether phosphate in examples 1-26). Further, the instant rejection provides evidence by the way of teachings of JP 814 that transparent ceramide comprising compositions that are similar to the instant compositions can be prepared without the need for anionic surfactants. Thus, one skilled in the art at the time of the instant invention was made would have been able to choose to prepare ceramide compositions with (1%) or without ionic surfactants and still obtain clear or transparent composition. Therefore, it would have been within the scope of a skilled artisan to include or exclude the anionic surfactants of Nakamura in the preparation of transparent stable compositions because JP 814 also provide transparent compositions and do not contain any anionic surfactants. While applicants argue that Nakamura requires 1-50% of ionic surfactants, applicants have not provided any evidence that instant compositions do not result in transparent compositions in the presence of anionic surfactants in amounts taught by Nakamura. On the other hand, the instant specification clearly states that one can employ anionic surfactants (including those described by Nakamura or EP 852). Further, the examiner notes that instant Application example 1 (table 3, page 27 of the application) includes 2% anionic surfactants (same as that employed by Nakamura i.e., sodium polyoxyethylene lauryl ether phosphate) and yet

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achieve transparent compositions. Applicants have not provided any arguments regarding the transparent compositions of JP 814 that lack anionic surfactants. Thus, instant rejection is not based on Nakamura alone and instead also provides a teaching of JP 814 that does not employ any ionic surfactants and yet achieve clear/transparent compositions of claimed ceramides. Further, JP 703 teaches compositions that have no ionic surfactants.

### ***Conclusion***

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/  
Primary Examiner, Art Unit 1611